DOCKET

AUG - 6 1997

Mr. Faisal Shah
General Counsel
Richardson Labs
P.O. Box 570
Meridian, Idaho 83860

Dear Mr. Shah:

This is in response to your letter of June 5, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements for your product, Arthred-G.

> Arthred-G provides enzymatically hydrolyzed collagen protein, glucosamine and chondroitin sulfate to supply the building blocks for cartilage.
> Arthred-G provides dual action nutritional support for optimal joint health.
> Arthred-G provides essential nutrition for cartilage repair processes.
> Arthred-G provides proactive nutritional support for cartilage degeneration.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, mitigate, prevent, or cure a disease, namely osteoarthritis, in that it "provides proactive nutritional support for cartilage degeneration." This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Seattle District Office, Office of Compliance, HFR-PA340
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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Innovation

RICHARDSON LABS.

Marketing

Quality

Science

June 5, 1997

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Dr. Elizabeth Yetley
Office of Special Nutritionals
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Dr. Yetley:

As required by Title 21, Section 343(r)(6) of the U.S.C.A, this letter serves as notification of the claims being made by Richardson Labs LLC, located at Post Office Box 570, Meridian, Idaho 83680, in regards to its Arthred-G™ product.

The claims being made by Richardson Labs LLC for Arthred-G ™ are as follows:

- Arthred-G™ provides enzymatically hydrolyzed collagen protein, glucosamine and chrondroitin sulfate to supply the building blocks for cartilage;
- Arthred-G™ provides dual action nutritional support for optimal joint health;
- Arthred-G™ provides essential nutrition for cartilage repair processes; and
- Arthred-G™ provides proactive nutritional support for cartilage degeneration.

If you have any questions, please feel free to contact the undersigned at (208) 893-6754.

Very truly yours,

Faisal Shah
General Counsel

cc: Edward D. Priddy

K30805

Mailing P.O. Box 570, Meridian, ID 83680 Shipping 3475 Commercial Court, Meridian, ID 83642 Phone 208-893-6700 Fax 208-884-3202